

K961454

JUL 25 1996

ATTACHMENT 4

AMMI  
MAGNI-GUARD - Splash Prevention Device  
510(k) Summary

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SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION  
UPON WHICH  
AN EQUIVALENCE DETERMINATION COULD BE BASED

SUBMITTER INFORMATION

NAME: American Medical Manufacturing, Inc. (AMMI) TELEPHONE: (818) 701-7171  
ADDRESS: 9410 DeSoto St. Unit J CONTACT: Mike Hoftman  
Chatsworth, CA 91311 DATE OF PREPARATION: April 11, 1996

DEVICE NAMES

NAME: AMMI MAGNI-GUARD™  
COMMON/USUAL NAME: SPLASH PREVENTION DEVICE  
CLASSIFICATION NAME (if known): Not Known

PREDICATE OR LEGALLY MARKETED DEVICES

Various Companies; Four inch Petri-Dish  
Various Companies; Clear Needle Counters  
Various Companies; Face Guards

DEVICE DESCRIPTION AND INTENDED USE

Magni-Guard functions in the same manner as predicate devices in that it provides protection to the surgical staff during surgical procedures. The basic scientific concept that forms the basis for the Magni-Guard is that it consists of a clear, rigid, see through plastic. The Guard is made from styrene or PETG. The clear guard has raised side walls throughout its circumference (identical to a Petri-Dish) to prevent the splashing of blood across the surgical suite. It further has an extended handle attached to the circular guard for the nurse to hold over the surgical site as required intermittently during the surgical procedure. The significant physical and performance characteristics of the devices are noted below.

Device/Design/Materials Used/Physical Properties: Magni-Guard includes the same components as other marketed predicate devices. The concept of use is to hold it with one hand over a surgical site before releasing clamps from blood vessel grafts or during heavy irrigation to prevent blood splashing.

## TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

| Characteristics                 | Petri-Dish                  | 1/2 Needle Counter Box      | Face Shield                    | AMMI                             |
|---------------------------------|-----------------------------|-----------------------------|--------------------------------|----------------------------------|
| Guard                           | Clear                       | Clear                       | Clear                          | Clear                            |
| Side Walls                      | Yes                         | Yes                         | n/a                            | Yes                              |
| Size                            | 4" Diameter                 | 3"x4" Rectangular           | 3"x6" Rectangular              | 4" Diameter                      |
| Holding                         | 1 or 2 Hands                | 1 or 2 Hands                | N/A - On Face                  | 1 Hand                           |
| Disposable                      | Yes                         | Yes                         | Yes                            | Yes                              |
| Sterile                         | Yes                         | Yes                         | Yes                            | Yes                              |
| Design                          | Round Guard with Side Walls | Rectangular with Side Walls | Rectangular without side Walls | Round with Side Walls and Handle |
| Mat'l Wall Thickness            | .030"                       | .055"                       | .005"                          | .030"                            |
| Materials                       | Styrene                     | Styrene                     | PETG                           | Styrene and PETG                 |
| Puncture Resistance             | Yes                         | Yes                         | Yes                            | Yes                              |
| Resistant to Impact Penetration | Yes                         | Yes                         | Yes                            | Yes                              |
| Side Wall Height                | .340                        | .305                        | No Side Walls                  | .325                             |